EXHIBIT 34

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re:
Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates To:

All Actions

MDL No.
15-2666 (JNE/FLM)

VIDEOTAPED DEPOSITION

OF

CHRISTOPHER NACHTSHEIM

Minneapolis, Minnesota

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Reported by:
Amy L. Larson, RPR
Job No. 113495

the question.

THE WITNESS: That would be the next best alternative.

BY MR. SACCHET:

Q. Why is that?

A. Here what we're doing with the -- with the randomized -- with a clinical trial is that we're going to actually put both -- both types of blankets in practice and we can look at -- look directly at infection rates that result from the two different conditions, and that's the -- that's the clinical study. If you're looking at -- if you want to know about infections, I think you're limited to looking at observational studies such as -- such as the one that we report on.

We did -- we did experimental studies on bubbles, but we can't do experimental studies on infections without -- without resorting to a clinical trial of some kind.

So I think that, yeah, I think you probably -- if you want to look at infections, I think you're -- I think you're

probably limited to observational data.

Q. Isn't it true that a well-designed observational study can render results extremely similar to a properly conducted randomized trial --

MS. GARCIA: Object --

BY MR. SACCHET:

Q. -- on the same subject matter?

MS. GARCIA: Object to the form of the question.

THE WITNESS: I think that can happen, but I don't believe that the level of proof reaches the same -- I don't think that the proof reaches the same level of rigor. There's just always that chance in observational studies that -- I mean, I think there's a greater chance that something -- a confounding factor might be present, something you just hadn't thought of.

BY MR. SACCHET:

Q. But it is possible that if statistical significance is found based on observational data, that that significance may be replicated in a randomized control trial?

A. Yes.

Q. So the observational data that is presented in the McGovern study is certainly valuable, is it not?

MS. GARCIA: Object to the form of the question.

THE WITNESS: I think it's valuable.

BY MR. SACCHET:

Q. That's why you published the observational data, correct?

A. Yes.

Q. You were previously asked about potentially confounding factors with respect to the observational data that was presented in the McGovern study, correct?

A. Correct.

Q. And some of those potentially confounding factors dealt with infection control measures, correct?

A. Correct.

Q. If we could turn to page 1540 of Exhibit 4, the McGovern study.

A. (Complies.)

Q. I want to make sure that we are on the same page with respect to the change that occurred as to the antibiotic regime. Would you agree that an antibiotic called Gentamycin was applied during the forced-air warming period from July 1st, 2008, to the end of February 2009? It's about halfway down the paragraph.

A. I see it. From July 2008 to February 2009 a single dose of Gentamicin 4.5 was given at -- at induction.

Q. Whereas, a combination of Gentamycin and Teicoplanin -- and I'd be surprised if any of us know how to pronounce it, but that's how I'm going to say it -- was applied during the end of the forced-air warming period and throughout the entire conductive fabric warming period, which would namely be March 1st, 2009, until January 2011, correct?

MS. GARCIA: Can you please point to where you're reading from?

MR. SACCHET: So I am interpreting what's said in this paragraph and based on what's presented in Figure 7 so --

MS. GARCIA: Okay. Then I'll

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object to the form of the question.
THE WITNESS: I -- I read this --
MR. SACCHET: I can walk through it slower.
THE WITNESS: Well, I read this to say that in March 2009 there was a change to the combination of the two drugs you've pronounced, and I don't believe there were any changes until the end of the study.
MR. SACCHET: Okay.
BY MR. SACCHET:
Q. So -- so we're clear, there was a period in which Gentamycin was applied to some forced-air warming patients, and then the antibiotic changed to a combination of Gentamycin and Teicoplanin that applied to some forced-air warming patients and all of the conductive fabric warming patients, correct?
A. Correct.
Q. Assuming the change in antibiotic did not affect infection rates between warming devices, would you still consider the antibiotic a confounding variable?

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MS. GARCIA: Object to the form of the question.
THE WITNESS: I'm going to assume that it has -- the change had no effect?
BY MR. SACCHET:
Q. Yeah, assume that the antibiotic had no effect on the infection rate. Would it still be a confounding variable?
MS. GARCIA: Object to the form of the question.
THE WITNESS: I don't think it would be -- I don't think it would be considered a confounding variable. I'm trying to think of how else it might have an impact, if it's not having an effect. I guess it -- no, I don't think it would be, yeah.
BY MR. SACCHET:
Q. One way that we could control for the -- let me strike that.
In order to determine whether the antibiotic had an effect on infection rates, we could control for the warming device --
A. Yes.

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Q. -- and evaluate whether infection rates between the changed antibiotic stayed the same or went up or down --
A. Correct.
Q. -- with that control device, correct?
A. (Nods head.)
MS. GARCIA: I'm going to object to the form of the question.
BY MR. SACCHET:
Q. Did you understand it?
A. Yes.
Q. If infection rates between the two groups were similar, that would tend to show that the antibiotic was not a confounding factor?
A. Correct.
MS. GARCIA: Object to the form of the question.
BY MR. SACCHET:
Q. Assume that Mr. Albrecht, who you previously mentioned was an expert in statistics and you had full confidence in his ability to analyze data presented in this article, informed you that he found a 2.8 percent infection rate in those who received Gentamycin, a single drug,

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but 3.1 percent of patients who received the combination of antibiotics, but also forced-air warming patients, with a nearly identical infection rate, would you determine that the antibiotic was a confounding factor?
MS. GARCIA: Object to the form of the question.
THE WITNESS: That would be strong evidence that it was not a confounding factor.
MR. SACCHET: Let's mark this.
(Whereupon, Exhibit 27 was marked for identification.)
BY MR. SACCHET:
Q. So just to be clear, if we look at this table that's presented here, we can see in the first line it presents antibiotic protocol 1 versus 2 for FAW, does it not?
A. It does.
Q. Assume that protocol 1 is the singular antibiotic, i.e. Gentamycin, and that protocol 2 is the combination of Gentamycin and Teicoplanin.
A. Uh-huh. Yes.

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Q. In this particular analysis, forced-air warming is held constant, correct?
A. Correct.
Q. And for forced air, protocol 1, the percent of patients developing infection was 2.8?
A. Correct.
Q. And for forced air, protocol 2, involving patients who received both Gentamycin and Teicoplanin, the infection rate was 3.1, correct?
A. Correct.
Q. And the p-value was 0.839, correct?
A. That's what's reported here.
Q. That's what's reported here. We could conclude, based on this data set of these numbers, that when the patient-warming device is held constant, that the change in antibiotic had no effect on infection rates, correct?
MS. GARCIA: Object to the form of the question.
THE WITNESS: Assuming there's sufficient power in those sample sizes, although they look fairly large to me, yes.

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BY MR. SACCHET:
Q. The patient population for forced-air protocol 1 was 389 patients, correct?
A. Correct.
Q. And the patient population for those receiving the combination was 678, correct?
A. Correct.
Q. Those are fairly large patient populations, correct?
A. Correct.
MS. GARCIA: Object to the form of the question.
BY MR. SACCHET:
Q. Another way to determine whether the antibiotic was a confounding variable would be to control the antibiotic, but evaluate different infection rates between different forced-air -- or different warming devices, correct?
A. Yes.
MS. GARCIA: Object to the form of that question also.
BY MR. SACCHET:
Q. And if the infection rates were still higher

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among those who received forced-air warming compared to those who received conductive fabric warming, that would tend to show the antibiotic did not substantially affect infection rates, correct?
A. Correct.
MS. GARCIA: Object to the form of the question.
BY MR. SACCHET:
Q. And if that's true, the change in antibiotic would also not be a confounding factor, correct?
A. Correct.
MS. GARCIA: Object to the form of the question.
BY MR. SACCHET:
Q. If I could --
MR. SACCHET: Could I ask your basis for the objection?
MS. GARCIA: I'm sorry?
MR. SACCHET: Could I ask your basis for the objection on form?
MS. GARCIA: Yes. You keep using the word, "determine," and you keep using the

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word, "show," and you keep using the word, "establish," and I'm objecting to the form of the question based on those terms.
MR. SACCHET: That's not going to pass muster in the court.
BY MR. SACCHET:
Q. As to the hypothetical I just presented, if you could turn your attention to the second line of the table.
MS. GARCIA: I'm sorry, to just be complete with my form objection, it's also an incomplete hypothetical.
MR. SACCHET: Fair enough.
BY MR. SACCHET:
Q. Antibiotic protocol 2 involved a combination have Gentamycin and Teicoplanin, correct?
MS. GARCIA: Object to foundation --
BY MR. SACCHET:
Q. -- for the sake of --
A. Yes.
MS. GARCIA: Excuse me. Object to foundation for that.
BY MR. SACCHET:

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Q. And the data here shows that 3.1 percent of patients who received forced-air warming in the combination antibiotic developed joint infections, correct?
A. Correct.
Q. Whereas, .9 percent of patients who received conductive fabric warming and the combination of antibiotics developed joint infections, correct?
A. Correct.
Q. By holding the antibiotic constant and discontinuing the use of forced-air warming, that resulted in a 71 percent decrease in joint infections, did it not?
MS. GARCIA: Object to the form of the question.
THE WITNESS: Yes, it did.
BY MR. SACCHET:
Q. That essentially matches the 73 percent decrease in infections that was noted in the McGovern article itself, does it not?
A. Correct.
MS. GARCIA: Object to the form of the question.

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BY MR. SACCHET:
Q. And based on the p-value of .0008, which is far less than .05, you would determine that difference to be statistically significant, would you not?
A. I would.
Q. So whether we control for the device or control for the antibiotic, based on this data set in Exhibit 27, would you determine that the antibiotic was not a confounding factor?
MS. GARCIA: Object to the form of the question, it's a lack of foundation, it's an incomplete hypothetical.
THE WITNESS: This data certainly supports that hypothesis.
BY MR. SACCHET:
Q. And if it were not a confounding factor, would there be any reason to deselect patients from the population of 1,437 accounted for in the McGovern study in order to exclude those who received a single antibiotic?
A. No.

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MS. GARCIA: Object to the form of the question.
BY MR. SACCHET:
Q. And if we were to do that and reduce the population, let's say, from the 1,473, or 37, I've forgotten which number it is, down to a number of let's say 500 patients, there could be concern about the powering of that population?
A. There could. There could be.
Q. Another confounding factor that was discussed this afternoon was a change in the thromboprophylaxis protocol, correct?
A. Yes. Can -- can you just remind me where that --
Q. Yeah, if we could turn to page 1540.
A. (Complies.)
Q. If you look at the bottom of the first full paragraph in the left-hand column, it states the thromboprophylaxis regimen from July 2008 to the end of July 2009 was Tinzaparin.
A. Uh-huh.
Q. Then it says from August 2009 to February

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2010, Rivaroxaban, which I'll represent is otherwise known as Xarelto, was provided from day one, but in February 2010 to the end of this study, patients were reverted to Tinzaparin, correct?
A. Yes.
Q. Assuming the change in the prophylaxis did not affect infection rates during the time of this study, i.e., Exhibit 4, would you still consider it a confounding variable?
A. No.
MS. GARCIA: Object to the form of the question.
(Whereupon, Exhibit 28 was marked for identification.)
MS. GARCIA: What number are we on?
MR. SACCHET: Twenty-eight, I believe.
THE COURT REPORTER: Correct.
MS. GARCIA: Thank you.
BY MR. SACCHET:
Q. Have you seen this document before, Professor?

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A. No, I have not.
Q. Was this document produced with the set of documents that you provided to 3M in response to the subpoena?
A. No.
Q. Does the bottom right-hand label of this document bear a Bates number of Nachtsheim --
A. It does.
Q. -- space 0000451?
A. It must have been attached to one of my e-mails. I -- I -- I don't remember seeing the document.
Q. Since you don't remember receiving or reading the document, let's go through it.
A. Okay.
Q. If you'd turn to the second page of text that bears the heading, "Introduction"; do you see that?
A. I do.
Q. Do you see the last paragraph at the bottom of that page?
A. "This multicenter study"?
Q. Correct. I'll read it out loud and you just confirm that we're on the same page. "This

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multicenter study based on prospectively collected national data aims to evaluate the surgically relevant complications of using either Rivaroxaban, or LMWH," which I'll represent means low molecular weight heparins, "as thromboprophylaxis, including wound complications, readmission and return to theater for deep infection, in addition to the incidents of major bleeds and EVT," correct?
A. Correct.
Q. Based on that statement, do you agree that at least two or three outcomes were measured, one being wound complications, another being return to theater for deep infection, and another being major bleeds?
A. I agree.
MS. GARCIA: I object to lack of foundation.
BY MR. SACCHET:
Q. If you could turn to the next page under, "Methods," in the third paragraph it states, "The primary outcome measure was wound complications," parens, "Including hematoma,

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superficial wound infection and deep infection requiring return to theater, RTT, within 30 days of procedure"; do you see that?
A. I do.
Q. And you see the designation that RTT involves a deep infection requiring a return to theater, correct?
A. Correct.
Q. Which is one of the independent variables that was mentioned in the prior paragraph that we read, correct?
MS. GARCIA: Object to the form of the question.
THE WITNESS: Correct. I think dependent variables.
MR. SACCHET: Okay. Noted.
BY MR. SACCHET:
Q. If we can now turn to the next page under, "Results," do you see that heading?
A. Yes, 456.
Q. It says, "During the study period, 2,762 patients received Rivaroxaban, and 10,361 received LMWH. Patient demographics are

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shown in table 1. There were significantly fewer wound complications in the LMWH group," parens, "2.81 percent versus 2.85 percent, OR equals .72, 95 percent confidence intervals between 0.58 to 0.90 with a p-value of .005. However, rates of RTT for infected wound washout were not significantly different." Do you see that?
A. I do.
Q. Assuming the truth of this study in what we just read, would you agree that Rivaroxaban, otherwise known as Xarelto, increased wound complications compared to low weight molecular heparins like Tinzaparin?
MS. GARCIA: Object to the form of the question, to an incomplete hypothetical and to a lack of foundation for this witness to opine about the meaning of this article.
THE WITNESS: It says there were significantly fewer wound complications in the LMH -- LMWH group. Is that what you're referring to?
BY MR. SACCHET:
Q. That's what I'm referring to. And the

p-value was a statistically significant value, correct?
A. Yes, correct.
Q. So there were fewer wound complications as a result of the use of a low weight molecular heparin --
A. Correct.
Q. -- compared to Rivaroxaban, correct?
A. Yeah, correct.
MS. GARCIA: Object to the form of the question.
BY MR. SACCHET:
Q. However, the study notes that rates for RTT, which we established to be a return to theater for --
A. Uh-huh.
Q. -- infections, were not significantly different; do you see that?
A. Correct. Yes, I do.
Q. Assuming the truth -- well, let me back up.
Would you also agree that the McGovern study, Exhibit --
MS. GARCIA: Four.
BY MR. SACCHET:

Q. -- 4, evaluated joint infections?
A. Yes.
Q. It did not evaluate wound complications, did it?
A. Correct, it did not.
Q. Assuming the truth of this study, would you ultimately agree that the change in protocol from Tinzaparin, which is an LMWH, to Xarelto, otherwise known as Rivaroxaban, and then back to Tinzaparin, did not significantly affect the infection rate?
MS. GARCIA: Object to the form of the question, to lack of foundation, and it's an incomplete hypothetical.
THE WITNESS: Assuming the study was carefully done and generalizable, yes.
BY MR. SACCHET:
Q. And assuming the study was well done and generalizable, would you agree that the change in thromboprophylaxis noted in the McGovern study, Exhibit 4, did not confound the infection rates?
MS. GARCIA: Object to the form of the question.

THE WITNESS: Assuming -- yes.
BY MR. SACCHET:
Q. And would you also conclude that, assuming the truth of this study, it would be improper to deselect all of the patients who received Xarelto, otherwise known as Rivaroxaban, from the patient population if the thromboprophylaxis was not a confounding variable?
MS. GARCIA: Object to the form of the question.
THE WITNESS: It doesn't seem justified in -- on the basis of these results.
BY MR. SACCHET:
Q. And, in fact, when the coauthors of the McGovern study were in the process of publication, are you aware that at numerous times they sought to collect additional data in support of the study?
A. I was not aware of that. I knew that -- I knew that they sought to run this study out in time.
Q. Are you aware that when Mr. Albrecht and

Dr. Reed collected additional data that went beyond January 2011 in the conductive fabric warming population, that the data still showed a significant decrease in infections when conductive fabric warming was used?
A. I'm aware of that.
Q. Assuming that --
MS. GARCIA: Can we take a break shortly?
MR. SACCHET: Yeah, give me two minutes.
BY MR. SACCHET:
Q. Assuming that neither the antibiotic nor the thromboprophylaxis protocol required control because they were not confounding factors as we discussed, you would be confident in the results of the observational study presented in the McGovern data?
MS. GARCIA: Object to the form of the question.
THE WITNESS: I'm confident that those weren't confounding factors, that those studies are well done. It doesn't rule out the potential for other confounding factors.